Docket No.: 65350(54086)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Michael V. Agrez

Application No.: 10/575,736 | Confirmation No.: 9415

Filed: October 11, 2006 | Art Unit: 1643

For: METHODS AND AGENTS FOR THE TREATMENT OF CANCER | Examiner: B. Duffy

RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

This Response to Restriction Requirement is submitted concurrently with a Preliminary Amendment that obviates the Examiner's objection to claims 88-91, 94-97, 99, 101, 103, and 107.

Claims 1 and 86-107 are pending in the instant application and are subject to restriction.

The Office Action, on page 2, requires restriction to one of the following groups under 35 U.S.C. §121:

Group I – Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e., prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ. ID NO:4.

Group II – Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e. prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:5.

Group III – Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e. prevention, of a cancer in a mammal wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:6.

Group IV – Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e., prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:7.

Group V – Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e. prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:8.

Group VI – Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e., prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:9.

Group VII – Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e. prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:10.

Group VIII – Claim 92, insofar as the claim is drawn to a method for prophylaxis, i.e. prevention, of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:11.

Group IX – Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, where cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:4.

Group X – Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:5.

Group XI - Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:6.

Group XII – Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:7.

Group XIII – Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:8.

Group XIV – Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:9.

Group XV – Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method

comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:10.

Group XVI – Claim 92, insofar as the claim is drawn to a method for treatment of a cancer in a mammal, wherein cancer cells of the cancer express a MAP kinase and the method comprises treating the mammal with an effective amount of a polypeptide that consists of SEQ ID NO:11.

In response to the restriction requirement set forth in the Office Action mailed April 1, 2009, Applicant hereby provisionally elects claims Group XII, Claim 92 for continued examination. Applicant respectfully traverses the requirements for restriction, and submits that the requirements are improper.

The Examiner alleges that the claims do not encompass a special technical feature. The Examiner characterizes the special technical feature as "treating a mammal that has cancer expressing a MAP kinase with an effective amount of a polypeptide that binds to a binding domain of the MAP kinase." The Examiner further alleges that this technical feature is described by Agrez et al., International Application No. 2001/000677 (hereinafter "Agrez"). Applicant respectfully disagrees. As outlined in the International Preliminary Report on Patentability, which was submitted on March 4, 2009, as Exhibit A in response to the Examiner's interview summary, the claimed invention is distinguished over Agrez (referred to in the IPRP as D1) because it is based on the surprising discovery that it is not necessary for the integrin to which the Map kinase binds to be expressed by a target cancer cell in order to inhibit growth of the cancer cells.

As further indicated in the IPRP, Agrez relates to the inhibition of the integrin/MAP kinase interaction. Hence, a person of ordinary skill in the art would have focused on inhibiting the physical association of the MAP kinase *with the integrin* as a treatment for cancer. In contrast, it is the *non-expression of the ß integrin* that is the subject of the present application. Therefore, a single, searchable, unifying aspect links all of the claims. The claims are all characterized by the single inventive concept of treating cells with a polypeptide as defined in claim 1, wherein the cells essentially do not express the relevant ß integrin subunit. Applicant notes that the peptides recited in claim 92 are either ß integrin fragments or fragments in which

the non-essential "linker region" of the fragments have been deleted (see, for example, claims 88 and 89). Nevertheless, the peptides all bind MAP kinase as required by claim 1. As such, the Restriction Requirement is not proper and restriction of the claims to a specific polypeptide has no sound basis because many other peptides can be employed as encompassed by claim 1. If the independent claims were limited to the use of a single particular peptide the value of the application would be substantially minimized.

In view of this, Applicant submits that a sufficient search and examination with respect to the subject matter of all claims can be made without serious burden. As the M.P.E.P. states:

> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. M.P.E.P. § 803 (8th ed., Rev. No. 2, May 2004).

That is, even if the above-enumerated groups of claims are drawn to distinct inventions, the Examiner must still examine the entire application on the merits because doing so will not result in a serious burden. This is especially true given the robust and extensive computerized search engines and databases at the Examiner's disposal. Accordingly, it is respectfully requested that the restriction requirement be reconsidered and the elected claim of Group XII be rejoined with those of Groups I-XI and XIII-XVI so that each of claims 1 and 86-107 may be presently examined.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. . 04-1105.

Dated: May 1, 2009

Respectfully submitted,

By_____

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